Claims

[c1] An anti-reflux valve prosthesis to be placed in an esophagus, the prosthesis comprising:

an annular fixation element to secure the prosthesis in the esophagus;

a one-way valve depending from the annular fixation element, the one way valve configured to allow orthograde passage therethrough and to inhibit retrograde passage of gastric contents; and

a gas permeable membrane to allow retrograde permeation of a gas therethrough.

[c2] The anti-reflux valve prosthesis of claim 1 wherein the prosthesis is configured to be perorally installed.

[c3] The anti-reflux valve prosthesis of claim 2 wherein the prosthesis is configured to be perorally removable.

[c4] The anti-reflux valve prosthesis of claim 1 wherein the gas permeable membrane is substantially liquid impermeable.

[c5] The anti-reflux valve prosthesis of claim 1 wherein the one-way valve is a sleeve valve.

[c6] The anti-reflux valve prosthesis of claim 1 wherein the prosthesis is comprised of a biologically inert material.

[c7] The anti-reflux valve prosthesis of claim 6 wherein the prosthesis is comprised of a fluorinated polymer.

[c8] The anti-reflux valve prosthesis of claim 1 wherein the valve is implanted in the esophagus of a patient with gastroesophageal reflux disease.

[c9] The anti-reflux valve prosthesis of claim 8 wherein the esophagus is cancer free.

[c10] An anti-reflux valve prosthesis to be placed in an esophagus, the prosthesis comprising:

an annular fixation element to secure the prosthesis in the esophagus;

a sleeve valve depending from the annular fixation element, the sleeve valve configured to allow orthograde passage therethrough and to inhibit retrograde passage of gastric contents; and

the sleeve valve comprises a plurality of magnets secured at a distal end thereof to facilitate closure of the sleeve valve.

[c11] The anti-reflux valve prosthesis of claim 10 further comprising a gas permeable membrane to allow retrograde permeation of gas therethrough.

[c12] The anti reflux valve prosthesis of claim 11 wherein said gas permeable membrane is substantially liquid impermeable.

[c13] An anti-reflux valve prosthesis for peroral implantation in the esophagus, the prosthesis comprising:

an annular body;

a valve depending from the annular body, said valve allowing orthograde passage therethrough and inhibiting retrograde passage of gastric contents; and

a plurality of retractable spikes spaced along a circumference of the annular body adjacent one end thereof.

[c14] The anti-reflux valve prosthesis of claim 13 wherein said valve is a sleeve valve.

[c15] The anti-reflux valve prosthesis of claim 14 wherein said sleeve valve comprises a plurality of magnets, the magnets secured at a distal end thereof to facilitate closure of the sleeve valve.

[c16] The anti-reflux valve prosthesis of claim 13 further comprising a gas permeable membrane to allow retrograde permeation of gas therethrough.

[c17] The anti-reflux valve prosthesis of claim 16 wherein the gas permeable membrane is substantially liquid impermeable.

[c18] The anti-reflux valve prosthesis of claim 13 wherein each of the spikes include a tip at a free end thereof and a base attached to the annular body.

[c19] The anti-reflux valve prosthesis of claim 18 wherein a dog is formed between

the base and the tip of each of the spikes.

[c20] The anti-reflux valve prosthesis of claim 19 wherein a plurality of keepers are positioned on an exterior surface of the annular body for receiving the dogs and locking the spikes in a deployed alignment.

[c21] The anti-reflux valve prosthesis of claim 10 wherein each of the spikes is outwardly bendable at the base between a retracted alignment and a deployed alignment.

[c22] The anti-reflux valve prosthesis of claim 21 wherein said retracted alignment is generally longitudinal.

[c23] The anti-reflux valve prosthesis of claim 21 wherein said deployed alignment is generally radially outward.

[c24] The anti-reflux valve prosthesis of claim 13 further comprising a tool to perorally insert the prosthesis into the esophagus.

[c25] The anti-reflux valve prosthesis of claim 13 further comprising a tool to perorally remove the prosthesis from the esophagus.

[c26] The anti-reflux valve prosthesis of claim 14 wherein the annular body is internally threaded.

[c27] The anti-reflux valve prosthesis of claim 13 wherein the valve is to relieve symptoms of a patient with Gastroesophageal reflux disease.

[c28] The anti-reflux valve prosthesis of claim 27 wherein the patient does not suffer from esophageal cancer.

[c29] A tool for implanting an anti-reflux valve prosthesis, wherein the prosthesis includes an annular body and retractable radial spikes therefrom, the tool comprising:

an inner tube and an outer tube, said tubes being generally concentrically aligned;

a nipple secured to a distal end of the inner tube, the nipple configured to be releasably coupled with the annular body; and

a headpiece secured to a distal end of the outer tube to engage the retractable spikes and outwardly extend them into position by advancing the headpiece into abutment with the nipple.

[c30] The tool of claim 29 wherein the outer tube is configured to be advanced or retracted as the outer tube is rotated with respect to the inner tube.

[c31] The tool of claim 30 further comprising a handle, said handle being secured adjacent to a proximal end of the inner tube for manipulation thereof.

[c32] The tool of claim 31 further comprising a second handle secured adjacent to a proximal end of the outer tube to facilitate rotation of the outer tube with respect to the inner tube.

[c33] The tool of claim 29 further comprising a fiber optic cable disposed within a central longitudinal passage of the inner tube for viewing the esophagus.

[c34] The tool of claim 29 wherein the headpiece includes a plurality of transverse passages formed therein in communication with a transverse bore in a wall of the inner tube and a central longitudinal passage.

[c35] The tool of claim 34 further including a vacuum source in communication with the central longitudinal passage.

[c36] A method for using a tool to perorally implant an anti-reflux prosthesis in an esophagus, the method comprising the steps of:

mounting the anti-reflux valve prosthesis onto a headpiece of the tool;
positioning the anti-reflux valve prosthesis in the esophagus;
deploying a plurality of radial spikes of the prosthesis;
pulling a vacuum across a longitudinal passage of the tool; and
drawing a lumen of the esophagus inwardly to facilitate impaction of the spikes.

[c37] The tool of claim 36 wherein the headpiece is configured to be removable and replaced with a crown, the crown configured to assist in the peroral removal of the prosthesis from the esophagus.

[c38] A tool for implanting an anti-reflux prosthesis in an esophagus, the tool comprising:

a means for mounting the anti-reflux valve prosthesis onto a headpiece of the tool;

a means for positioning the anti-reflux valve prosthesis in the esophagus;

a means for deploying a plurality of radial spikes with the tool

a means for pulling a vacuum across a longitudinal passage of the tool; and

a means for drawing a lumen of the esophagus inwardly for facilitating impaction of the spikes.

[c39] A method for implanting an anti-reflux valve prosthesis in an esophagus, the method comprising the steps of:

perorally inserting and positioning the anti-reflux valve prosthesis into the esophagus;

deploying a plurality of spikes, the spikes depending radially from the anti-reflux prosthesis; and

impaling the esophagus upon the spikes to hold the prosthesis in place.

[c40] The method of claim 39 further comprising using a vacuum to assist in impaling the esophagus upon the spikes.

[c41] A tool for implanting an anti-reflux prosthesis in an esophagus, the tool comprising:

a means for perorally inserting and positioning the anti-reflux valve prosthesis into the esophagus;

a means for deploying a plurality of spikes, the spikes depending radially from the anti-reflux prosthesis; and

a means for impaling the esophagus upon the spikes to hold the prosthesis in place.

[c42] A method for using a tool to implant an anti-reflux valve prosthesis into an esophagus, the method comprising the steps of:

releasably engaging a nipple of the tool with an annular body of the prosthesis, the prosthesis having a plurality of retractable embedment

spikes;

perorally inserting the valve prosthesis into the esophagus near a gastroesophageal junction;

extending the spikes fully outward into a deployed alignment for engagement with a lumen of the esophagus;

uncoupling the nipple from the prosthesis; and

withdrawing the tool from the esophagus.

[c43] The method of claim 42 further comprising actuating a vacuum source to draw a wall of the lumen inwardly and facilitate engagement of the spikes therein.

[c44] A tool for implanting an anti-reflux prosthesis in an esophagus, the tool comprising:

a means for releasably engaging a nipple of the tool with an annular body of the prosthesis, the prosthesis having a plurality of retracted embedment spikes;

a means for perorally inserting the valve prosthesis in to the esophagus near a gastroesophageal junction;

a means for extending the spikes fully outward into the deployed alignment for engagement with a lumen of the esophagus;

a means for uncoupling the nipple from the prosthesis; and

a means for withdrawing the tool from the esophagus.

[c45] A tool for extracting an anti-reflux valve prosthesis, wherein the prosthesis includes an annular body and extended radial spikes therefrom, the tool comprising:

an inner tube and an outer tube, said tubes being generally concentrically aligned;

a nipple secured to a distal end of the inner tube, the nipple configured to be releasably coupled with the annular body; and

a crown secured to a distal end of the outer tube, the crown having a plurality of tangentially projecting shoes to receive and retract the extended radial spikes.

[c46] The tool of claim 45 further wherein the outer tube is configured to be

advanced or retracted as the outer tube is rotated with respect to the inner tube.

[c47] The tool of claim 46 further comprising a handle, the handle being secured adjacent to a proximal end of the inner tube for manipulation thereof.

[c48] The tool of claim 47 further comprising a second handle secured adjacent to a proximal end of the outer tube to facilitate movement of the outer tube with respect to the inner tube.

[c49] The tool of claim 45 further comprising a fiber optic cable disposed within a central longitudinal passage of the inner tube for viewing the esophagus.

[c50] The tool of claim 45 further comprising an overtube having a shield of enlarged diameter at a distal end thereof, wherein the overtube is slidable over the outer tube to receive the plurality of spikes to facilitate removal of the prosthesis from the esophagus.

[c51] The tool of claim 50 wherein the shield is tapered from a larger diameter at a distal end to a smaller diameter at a proximal end.

[c52] The tool of claim 45 wherein the crown is configured to be removable and replaced with a headpiece, the headpiece configured to assist in reinstalling the prosthesis into the esophagus.

[c53] A method for using a tool to extract an anti-reflux valve prosthesis from an esophagus, the method comprising the steps of:

perorally inserting the tool into the esophagus, wherein the tool comprises a nipple and a crown;

engaging the nipple into an annular body of the prosthesis, wherein the prosthesis includes a plurality of extended embedment spikes;

advancing the crown with respect to the nipple, the crown configured to retract the embedment spikes; and

removing the tool and engaged prosthesis from the esophagus.

[c54] The method of claim 53 further comprising advancing a shield over the spikes to place the spikes into a retracted position.

[c55] A tool for extracting an anti-reflux prosthesis from an esophagus, the tool comprising:

a means for perorally inserting the tool into the esophagus, wherein the tool comprises a nipple and a crown;

a means for engaging the nipple into an annular body of the prosthesis, wherein the prosthesis includes a plurality of extended embedment spikes;

a means for advancing the crown with respect to the nipple, the crown configured to retract the embedment spikes; and

a means for removing the tool and engaged prosthesis from the esophagus.

[c56] An anti-reflux valve prosthesis for peroral implantation in the esophagus, comprising:

an annular body comprising a biologically inert polymer;

a valve depending from the annular body for allowing orthograde passage therethrough and inhibiting retrograde passage of gastric contents;

a plurality of substantially rigid spikes spaced along a circumference of the annular body adjacent one end thereof and extending radially outwardly from the annular body;

each spike comprising a tip at a free end thereof and a base at the other end attached to the annular body;

wherein each spike is temporarily inwardly bendable for implantation and has memory to return to the radially outwardly extending position.

[c57] A tool for implanting the anti-reflux valve prosthesis of claim 56 wherein the annular body is internally threaded and the spikes are attached to a proximal end of the annular body, comprising:

an inner tube;

a nipple secured to a distal end of the inner tube for releasably threadably coupling the annular body;

a handle secured adjacent to a proximal end of the inner tube for manipulation thereof;

an overtube slideable along and receiving the inner tube;

a handle secured to a proximal end of the overtube for manipulation thereof;

a shield attached to a distal end of the overtube longitudinally movable between a first position for receiving the fixation spikes in the inwardly bent configuration during peroral insertion into the esophagus, a second position for releasing the fixation spikes, and a third position for facilitating return of the fixation spikes to the memory position.

[c58] A method for using the tool of claim 57 for implanting the anti-reflux valve prosthesis, comprising the steps of:

threadably engaging the nipple in the annular body;

bending the spikes inwardly and positioning the shield in the first position over the spikes;

perorally inserting the valve prosthesis into the esophagus near the gastroesophageal junction;

while holding the valve prosthesis in place, moving the shield into the second position to release the spikes to return to the memory position;

optionally moving the shield into the third position to facilitate return of the spikes into the memory position to facilitate engagement of the spikes in a wall of the esophagus;

rotating the inner tube with respect to the annular body to uncouple the nipple;

withdrawing the tool from the esophagus.

[c59] The method of claim 58 further comprising moving the shield into the third position to facilitate return of the spikes into the memory position to facilitate engagement of the spikes in a wall of the esophagus.

[c60]

A tool for extracting the anti-reflux valve prosthesis of claim 56 wherein the annular body is internally threaded and the spikes are attached to a proximal end of the annular body, comprising:

inner and outer concentric tubes;

a nipple secured to a distal end of the inner tube for threadably coupling the annular body;

a handle secured adjacent to a proximal end of the inner tube for manipulation thereof;

wherein the inner tube and the outer tube are in threaded interengagement for advancement of the outer tube by rotating the outer tube with respect to the inner tube;

a crown secured to a distal end of the outer tube and having a plurality of tangentially projecting shoes disposed on a distal end of respective longitudinal arms spaced along a circumference of the crown in correspondence with the spikes for bending the fixation spikes inwardly;

an overtube having a shield of enlarged diameter at a distal end thereof, wherein the overtube is slidable over the outer tube to receive the plurality of inwardly bent spikes within the shield to inhibit laceration of the esophagus during movement of the prosthesis.

[c61] A method for using the tool of claim 60 for extracting the anti-reflux valve prosthesis, comprising the steps of:

perorally inserting the tool into the esophagus and threadably engaging the nipple in the annular body of the prosthesis;

while holding the inner tube in place, rotating the outer tube with respect to the inner tube to advance the crown with respect to the nipple, engage the spikes with the shoes and bend the fixation spikes radially inwardly;

advancing the overtube to position the shield over the inwardly bent spikes;

withdrawing the tool and the prosthesis from the esophagus.

[c62] A tool for implanting an anti-reflux prosthesis in an esophagus, the tool comprising:

a means for bending a plurality of spikes inwardly and a means for positioning a shield in a first position over the spikes;

a means for perorally inserting the prosthesis into the esophagus near a gastroesophageal junction;

a means for moving the shield into a second position while holding the prosthesis in place to release the spikes into a memory position;

a means for rotating an inner tube of the tool with respect to an annular

body of the prosthesis to uncouple a nipple of the tool from the prosthesis; and

a means for withdrawing the tool from the esophagus.

[c63] A tool for extracting an anti-reflux prosthesis from an esophagus, the tool comprising:

a means for perorally inserting the tool into the esophagus and threadably engaging a nipple of the tool in an annular body of the prosthesis;

a means for rotating an outer tube of the tool with respect to an inner tube of the tool while holding the inner tube in place to advance a crown of the tool with respect to the nipple, to engage a plurality of spikes of the prosthesis with a plurality of shoes of the crown, and to bend the spikes radially inwardly;

a means for advancing an overtube of the tool to position a shield of the tool over the inwardly bent spikes; and

a means for withdrawing the tool and the prosthesis from the esophagus.